

**NHSLA Risk Management Standards
for
Acute Trusts
Primary Care Trusts
and
Independent Sector Providers of NHS Care**

2009/10



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Supporting Information

Handbooks and template policy documents have been developed to assist organisations in demonstrating compliance with the NHSLA Risk Management Standards. These can be found at www.nhsla.com/publications.

Handbooks - These provide supporting information for each criterion including reference sources and additional guidance.

Template policy documents - These have been created for a number of the criteria and provide a framework within which to develop policies, procedures, etc.

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3. INTRODUCTION

- 3.1 The NHS Litigation Authority (NHSLA) is a Special Health Authority, which was established in 1995 to administer the Clinical Negligence Scheme for Trusts (CNST) and thereby provide a means for NHS organisations to fund the cost of clinical negligence claims. Almost immediately the NHSLA's role expanded to cover clinical claims arising from incidents occurring before 1995, known as the Existing Liabilities Scheme (ELS). In 1999 the Liabilities to Third Parties Scheme (LTPS) and Property Expenses Scheme (PES), together known as the Risk Pooling Schemes for Trusts (RPST), were established to fund the cost of legal liabilities to third parties and property losses.
- 3.2 The promotion of good risk management, governance and assurance are integral components of the NHSLA schemes.
- 3.3 Membership of the schemes is voluntary and open to all NHS trusts, NHS foundation trusts and PCTs in England. Funding is on a pay-as-you-go non profit basis, and organisations receive a discount on their scheme contributions where they can demonstrate compliance with the relevant NHSLA risk management standards. Currently, contributions for independent sector providers of NHS care through Independent Sector Treatment Centres (ISTCs) and as part of the Extended Choice Network (ECN) are collected via membership of the referring PCT.
- 3.4 There are NHSLA risk management standards for each type of NHS health care organisation: acute, ambulance, mental health & learning disability, primary care trusts and independent sector providers of NHS care. The standards for acute and primary care trusts and the independent sector are set out within this manual. The standards for ambulance and mental health & learning disability trusts can be found in separate manuals. The standards are designed to address organisational, clinical, and non-clinical/health and safety risks.
- 3.5 All NHS acute and specialist hospital trusts, primary care trusts and independent sector providers of NHS care are required to be assessed against these standards in accordance with the timetable set out in 4.6 below.
- 3.6 In September 2008, the NHSLA published proposals for its future assessment of PCTs. The fundamental changes taking place within primary care meant that it was no longer appropriate for all PCTs to be assessed against the NHSLA risk management standards. From 2009/10 those PCTs providing clinical services that will be subject to mandatory assessment by the NHSLA will be identified on the basis of risk using information such as services provided, contributions to the NHSLA schemes and claims history. However, other PCTs providing clinical services may choose to be assessed against the standards. Further information on the assessment of PCTs, which will form an addendum to this manual, will be available on the NHSLA website from April 2009.
- 3.7 With the agreement of the Department of Health, the mandatory assessment of independent sector providers of NHS care via ISTCs and the ECN has been suspended by the NHSLA until April 2010, although organisations may request an assessment during 2009/10. Further information on the assessment of these organisations, which will form an addendum to this manual, will be available on the NHSLA website from April 2009.
- 3.8 The NHSLA issues separate clinical (CNST) standards against which maternity services are also assessed where these are provided by the organisation. In these circumstances CNST contributions are split between "maternity" and all other clinical services, with discounts earned from each in accordance with their respective assessment outcomes.

- 3.9 The standards and assessment process are designed to:
- provide a structured framework within which to focus effective risk management activities in order to deliver quality improvements in organisational governance, patient care and the safety of patients, staff, contractors, volunteers and visitors;
 - increase awareness and encourage implementation of the national agenda for the NHS;
 - encourage and support organisations in taking a proactive approach to improvement;
 - reflect risk exposure and empower organisations to determine how to manage their own risks;
 - contribute to embedding risk management into the organisation's culture;
 - reduce the level of claims by reducing the number of adverse incidents and the likelihood of recurrence;
 - assist in the management of adverse incidents and claims;
 - provide assurance to the organisation, other inspecting bodies and stakeholders, including patients.
- 3.10 If organisations (other than independent sector providers of NHS care whose contributions are collected via membership of the referring PCT) comply with the standards, they will benefit from the investment in risk management by paying lower scheme contributions.
- 3.11 The NHSLA is a full signatory to the [Concordat between bodies inspecting, regulating and auditing healthcare](#) and these standards and assessments reflect the principles of the *Concordat* which aims to support improvement in health services while minimising the disruption and duplication of inspection.
- Results and findings from NHSLA assessments are used in a variety of ways by other bodies. These include the Health and Safety Executive, Monitor, the National Institute for Health and Clinical Excellence and the NHS Security Management Service. Prior to its planned merger into the Care Quality Commission in April 2009, the Healthcare Commission used the findings of NHSLA assessments to inform the annual health check.
- Elements of the NHSLA assessment take assurance from work undertaken by auditors on behalf of the Audit Commission and compliance with the Postgraduate Medical Education Training Board (PMETB) minimum requirements for clinical supervision set out in Domain 6 of the PMETB generic standards for training.
- 3.12 A wide range of NHS and other organisations, risk managers and healthcare professionals have contributed to and been consulted on the development of these standards and the assessment process. The NHSLA gratefully acknowledges their valuable input.
- 3.13 Further information about the NHSLA can be found on the NHSLA website at www.nhsla.com.
- 3.14 A number of learning events are provided to help organisations achieve compliance with the standards. Details of learning events, advice on the standards and general aspects of risk management, and copies of NHSLA publications, can be found on the NHSLA website.
- 3.15 The NHSLA is constantly striving to improve the usability of its risk management standards manuals, and would welcome your feedback. Please email Stk.NHSLAssessment@dnv.com to tell us of known or suspected errors or

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omissions, suggestions for improvement, general comments or queries relating to any of the standards, criteria, or supporting information. Any resulting changes will be incorporated into the next version of the manual.

4. GENERAL PRINCIPLES

- 4.1 The standards contained within this manual will be updated on an annual basis, with a revised version available on the NHSLA website in January, to be assessed against from April.
- 4.2 Whilst separate CNST standards exist for maternity services, organisations which provide maternity services will also need to demonstrate application of the relevant NHSLA standards to all services, including maternity.
- 4.3 The number of standards and criteria will remain static; if a new criterion is added, an existing one will be removed.
- 4.4 When a new criterion is introduced or significant changes made to an existing criterion it will normally be piloted for one year to allow organisations preparation time before being formally assessed against the requirements. A list of the risk areas which may be piloted in future years is contained in [Section 9 - Overview of Proposed Risk Areas](#).
- 4.5 Assessment against the standards, in accordance with the following conditions, is a mandatory requirement of scheme membership.
- 4.6 Organisations will be assessed according to the following programme as a minimum:
- Level 0 organisations must be assessed on an annual basis until such time as they achieve Level 1.
- Level 1 organisations must be assessed against the standards at least once in any two year period.
- Level 2 and 3 organisations must be assessed against the standards at least once in any three year period.
- However, if an organisation fails an assessment it will be required to be assessed at the level assigned in the following financial year (see table in 5.13). As indicated in 4.19 organisations that drop to Level 0 or fail to attain Level 1 must undergo an informal visit within six months of the date of their last assessment.
- In exceptional circumstances, the NHSLA may also require organisations to be assessed outside the specified schedule.
- Wholly new organisations and those which have undergone significant restructuring must choose either a formal assessment or an informal visit within the first twelve months of their establishment or the restructuring. If an informal visit is chosen, a formal assessment must take place within 24 months of the organisational changes.
- 4.7 Organisations complying with the standards (other than independent sector providers of NHS care whose contributions are collected via membership of the referring PCT) will receive a discount from both their CNST and RPST contributions. The discounts are:
- | | |
|---------|-----|
| Level 1 | 10% |
| Level 2 | 20% |
| Level 3 | 30% |
- The appropriate discount will be applied from the beginning of the financial quarter following the date of the assessment visit.
- Those organisations assessed as complying with the standards at Level 1 will receive a discount for two years. Those assessed as complying with the standards at Level 2 or 3 will receive a discount for three years.

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Where an organisation drops to a lower level before expiry of the two or three year period, the risk management discount will be determined by the new level from the beginning of the following financial quarter.

- 4.8 Organisations will be assigned an assessment quarter based on the date of their previous assessment, e.g. if an organisation was last assessed in October its assessment quarter will be October to December. Organisations will be assessed within this assigned quarter, other than when they request an assessment earlier in the financial year.

Level 2 and 3 assessments will not, other than in exceptional circumstances, be conducted in March.

- 4.9 Organisations may only be assessed against the standards once in any financial year.
- 4.10 Refusal by an organisation to be assessed in accordance with the above timetable may result in the organisation being deemed to be at Level 0 and may lead to a refusal by the NHSLA to provide indemnity.
- 4.11 Organisations undergoing an assessment may be assessed at their existing level or may choose to be assessed at a lower or the next highest level. Organisations are strongly recommended to discuss the level at which they are planning to be assessed with their allocated assessor(s) to determine the organisation's readiness for assessment. As detailed in 5.13, it is important to note that organisations which perform badly at assessment will drop to a lower level and can potentially drop to Level 0.
- 4.12 Organisations undergoing significant restructuring (including mergers, acquisitions of services, etc.) will be allocated an assessment level by the NHSLA immediately post event. This will normally be determined by the level of the lowest component organisation and be valid for a maximum of two years.
- 4.13 When an organisation has achieved Level 1 or 2, it may apply for assessment at the next level from the following financial year. However, in order to ensure that their systems are embedded, organisations are advised to wait at least two years before being assessed at the next level.
- 4.14 If an organisation wishes to be assessed at a higher level between mandatory assessments, the onus is on the organisation to contact their assessor to book an assessment date.

Where a mandatory assessment is due, the assessor will contact the organisation, giving a minimum of three months notice of the intended assessment. However, the organisation may choose to contact their assessor to book a date for the assessment. Assessors will do their best to accommodate requests for visits at a time most convenient for the organisation, but to improve the choice of dates organisations should discuss this with their assessor as early as possible. Assessments may not however be booked more than twelve months in advance.

As detailed in 4.8, Level 2 and 3 assessments will not be conducted in March.

- 4.15 When booking an assessment, organisations must state the level at which they wish to be assessed. All requests for a change to a lower level assessment will be accepted, but must be notified to the assessor at least one month before the assessment. Organisations wishing to change to an assessment at a higher level must put their request in writing to their assessor for consideration a minimum of three months prior to the assessment date.
- 4.16 To assist organisations in preparing for assessment, an evidence template has been produced which is in electronic spreadsheet format. There is a single template

workbook encompassing the three assessment levels. The template allows organisations to conduct self-assessments and is also used by the assessors to record scores and findings. Further guidance on the use of the template can be found on the NHSLA website at www.nhsla.com/publications.

- 4.17 In the year(s) between formal assessments, organisations are encouraged to undertake a self-assessment against the standards using the appropriate level on the evidence template. This template can be used to create action plans to assist the organisation in preparing for future assessments and/or informal visits.

It is recommended that action plans should be completed following each assessment and/or informal visit, and that these should include realistic timescales and designated responsibilities for taking the actions forward. After completion the organisation may want to confirm the actions with their assessor as these will be reviewed at subsequent assessments and, in accordance with the [Concordat between bodies inspecting, regulating and auditing healthcare](#), may well be requested by other organisations for their reviews. The action plan should therefore be kept up to date and readily available.

- 4.18 Organisations can request one informal visit from their assessor in each financial year, subject to a reasonable notice period, to provide focused advice and guidance in relation to the standards and to monitor progress against the organisation's action plan. Informal visits may not take place within three months of a forthcoming assessment. Organisations due to be assessed between April and June may have two informal visits during the previous financial year. Following the visit, the organisation should update their action plan to incorporate any recommendations agreed with the assessor. As no formal report will be issued, the action plan must be forwarded to the assessor within three months of the visit.

- 4.19 Organisations that drop to Level 0 or fail to attain Level 1 must undergo an informal visit within six months of the date of the assessment. The purpose of this visit is to provide support and monitor progress against the organisation's action plan for achieving compliance. Prior to the visit the organisation will be required to submit an action plan to the assessor to inform the visit.

Following the visit, the organisation should update their action plan to incorporate any recommendations agreed with the assessor. As no formal report will be issued, the action plan must be forwarded to the assessor within one month of the visit.

- 4.20 Where there are concerns about performance between assessments, the NHSLA may visit the organisation to address these.
- 4.21 If an organisation cancels an assessment or informal visit without good reason and/or giving reasonable notice, the NHSLA reserves the right to recharge non refundable accommodation and travel expenses incurred by the assessor(s).
- 4.22 The NHSLA will publish assessment results, on both an individual and aggregate basis, on its website.

In accordance with the principles of the [Concordat between bodies inspecting, regulating and auditing healthcare](#) to which the NHSLA is a signatory, the NHSLA will also publish on its website the reports which are produced following assessments. If the organisation wishes to raise any concerns as to the wording and/or factual accuracy of the report, these should be notified to the assessor within four weeks of the date of receipt of the report. It will not be possible to make any additions to the report.

Further information about assessments may be disclosed under the Freedom of Information Act 2000.

4.23 Organisations may wish to publish information relating to their assessments on their own public websites. Such information might include assessment reports or minutes of meetings where assessments are discussed. The NHSLA recognises this as good practice but would request that neither NHSLA nor DNV staff be named in such documents. In publishing assessment related information on their websites, organisations are reminded that they have a duty to ensure the accuracy of such information.

4.24 Networking and sharing between organisations is important. On request, your assessor may be able to provide you with information about organisations that have demonstrated clear and comprehensive systems for achieving compliance with specific criteria.

Template documents have been created for a number of the criteria. These templates provide a framework within which to develop policies, procedures, etc. to support best practice and to assist organisations in complying with the standards, but their use is entirely optional. They are available for downloading from the NHSLA website at www.nhsla.com/publications.

4.25 The assessment team is always happy to answer questions by email or telephone on specific aspects of the standards. However, the assessors are not in a position to be able to review in full documentation submitted to them outside of a formal assessment or informal visit.

It is always best to contact the assessor allocated to your organisation, although other members of the assessment team will be able to provide some assistance. There is a [contacts list](#) for the assessors and NHSLA Risk Management team in section 2 of this manual.

In order to ensure that the independence of the assessors is not compromised, and that all organisations are dealt with on an equitable basis, general risk management advice cannot be given to individual organisations.

4.26 As a specialist provider of services for managing risks, DNV may bid and undertake work for organisations that are subject to assessment against the NHSLA standards. The contract between the NHSLA and DNV contains a clause on managing conflicts of interest and procedures to be followed in the event of an actual, potential or perceived conflict of interest have been agreed between the two parties. Further information on this subject can be obtained from the [NHSLA Risk Management Director](#).

5. MEASURING PERFORMANCE

- 5.1 The standards are set out in full in this manual, and it is essential that in preparing for an assessment organisations refer to these and the minimum requirements therein. In addition, organisations are advised to consider the Level 2 and 3 requirements when addressing the Level 1 criteria, to ensure that the objectives the organisation sets itself at Level 1 are measurable and achievable.
- 5.2 Each of the three levels is a distinct assessment containing its own individual question sets and scored on a stand-alone basis. Although lower level(s) will not be reassessed as the organisation progresses, a completed evidence template and documents for the Level 1 standards must be available on the assessment days irrespective of the level being assessed.
- 5.3 As the Level 1 assessment is only concerned with the existence of the minimum requirements for each criterion, the quality of these will not be rigorously tested until the Level 2 assessment. Therefore, compliance at Level 1 should not be seen as an indication that the organisation will be able to demonstrate compliance at Level 2 or that it is effectively managing risks.
- 5.4 The progression of organisations through the standards is logical and follows the development, implementation, monitoring and review of policies and procedures.

Level 1 – Documenting (Policy)

This demonstrates that the process for managing risks has been described and documented.

Level 2 – Implementing (Practice)

This demonstrates that the process for managing risks, as described in the approved documentation, is in use. Evidence should be provided for a number of departments and/or staff groups and/or patient types, etc. The evidence may include risk assessments, records, e.g. training, medical device inventories, incident reports, completed proformas, evaluations, etc.

Level 3 – Monitoring (Performance)

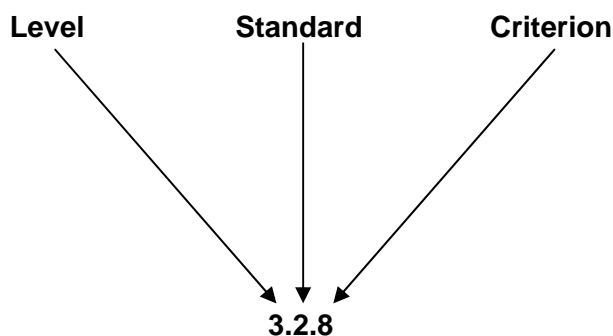
This demonstrates whether or not the process for managing risk, as described in the approved documentation, is working across the entire organisation. Where failings have been identified, action plans must have been drawn up and changes made to reduce the risks. Monitoring is normally proactive - designed to highlight issues before an incident occurs - and should consider both positive and negative aspects of a process.

- 5.5 Most of the Level 1 criteria ask for a process for monitoring compliance with the minimum requirements to be included in the relevant approved document(s). Although any document(s) with an approved/reviewed date prior to 1st April 2008 should ideally contain this information, compliance will still be awarded if all the other minimum requirements are met. Any documents approved/reviewed on or after this date must contain the information or compliance cannot be awarded.

At Level 3 compliance will be awarded if the organisation can demonstrate whether or not the process for managing risk, as described in the approved documentation, is working across the entire organisation even if this process is not described in documents approved prior to 1st April 2008. Any documents approved/reviewed on or after this date must contain the information or compliance cannot be awarded.

- 5.6 Each level contains five standards and within each standard there are ten criteria which are equally weighted.

- 5.7 The convention for referring to the individual criteria is as follows:



- 5.8 For all organisations undergoing an assessment against the standards, there is a single scoring system. The pass mark at each level is 40 out of 50 criteria with no fewer than seven criteria passed in any one standard. The level of compliance achieved will be determined in accordance with the table at 5.13.
- 5.9 Each criterion has a title, which outlines the risk issue to be addressed, followed by a list of the minimum requirements that the assessor(s) would expect to see being met in order to award compliance with the criterion. The minimum requirements at Level 1 which are carried forward to Levels 2 and 3 are highlighted in bold. Minimum requirements which are carried forward to higher levels but with a slightly different emphasis are highlighted in bold italics. It is important to note that the NHSLA may change the Level 1 requirements carried forward for assessment at Levels 2 and 3 either wholly or in part at any time in the future. [Guidance on collating evidence for an assessment](#) has been compiled to assist organisations in preparing for an assessment and can be found in section 7 of this manual.
- 5.10 The NHSLA Risk Management Handbooks provide supporting information for each criterion and can be found at www.nhsla.com/publications. The handbooks include documentation to support the rationale for including the criterion (such as national recommendations and claims information), and materials to assist the organisation in achieving compliance with the criterion, i.e. references and additional guidance.
- 5.11 A [Clarification of Terms](#) section has been compiled to define the words and phrases used in the manual to which a specific meaning applies in the context of the standards and assessments. These terms appear in colour and italics in the standards.
- 5.12 Evidence in support of a criterion must be in place and effective at the time of assessment. Draft documentation, or planned or proposed systems that have not been implemented, will not be admissible.

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5.13 Assessment scoring table:

Assessment Scoring Table											
			Lower Level			Existing Level			Higher Level		
Existing NHSLA Level			2	3	3	1	2	3	0	1	2
Level Applied for			1	1	2	1	2	3	1	2	3
Scoring Range	40 - 50	Outcome*	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
		Level Achieved	1	1	2	1	2	3	1	2	3
		Time frame for reassessment	2yrs	2yrs	3yrs	2yrs	3yrs	3yrs	2yrs	3yrs	3yrs
		Level(s) organisation can next be assessed at	1 or 2	1 or 2	1, 2 or 3	1 or 2	1, 2 or 3	1, 2 or 3	1 or 2	1, 2 or 3	1, 2 or 3
	30 - 39	Outcome	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail
		Level Achieved	0	0	1	0	1	2	0	1	2
		Time frame for reassessment	1yr	1yr	1yr	1yr	1yr	1yr	1yr	1yr	1yr
		Level(s) organisation can next be assessed at	1	1	1	1	1	1 or 2	1	1	1 or 2
	29 or less	Outcome	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail
		Level Achieved	0	0	0	0	0	0	0	0	0
		Time frame for reassessment	1yr	1yr	1yr	1yr	1yr	1yr	1yr	1yr	1yr
		Level(s) organisation can next be assessed at	1	1	1	1	1	1	1	1	1

* To pass an organisation must score no fewer than seven criteria in any one standard.

6. ASSESSMENT PROCEDURE

- 6.1 Assessors are employed by DNV for the sole purpose of undertaking assessments or risk management projects on behalf of the NHSLA.
- 6.2 Each assessor is allocated a number of organisations, on a regional basis. The assessor will act as the organisation's dedicated contact point and will be responsible for conducting assessments, informal visits and for answering any queries relating to the standards and assessment process. Where assessments are conducted by two assessors the organisation's allocated assessor will lead the assessment process.
- 6.3 An assessor will not be allocated an organisation where they have been employed in the past five years.
- 6.4 It is vital that organisations provide DNV with an up to date name and contact details of a nominated individual who will be responsible for arranging and coordinating assessments. Any important announcements and invitations to learning events will be sent to this individual.
- 6.5 Assessments at all levels comprise two days on site. When a date for the assessment has been agreed, the assessor will write to the contact within the organisation confirming the date and setting out a proposed programme for the assessment. Whilst documentation will not be reviewed in advance of the assessment visit, the organisation will be required to email its risk management strategy to the assessor ten working days prior to the assessment date to enable the assessor(s) to prepare for the assessment.
- On arrival for the assessment the evidence template will need to be made available to transfer onto the assessor(s) laptop(s), e.g. via a data stick. If any problems are foreseen with this data transfer the organisation should contact the assessor in advance of the assessment.
- The assessor(s) will work through the standards, evaluating the evidence provided and recording the findings on the evidence template completed by the organisation.
- 6.6 Organisations being assessed at Levels 2 or 3 will also need to complete a Level 1 template and provide related evidence. The assessor(s) will need to refer to (but not assess) the documents required for a Level 1 assessment.
- 6.7 Documentary evidence, where required, may be provided in electronic or paper format (or a combination of both).
- 6.8 The evidence template should be completed. The template can be found on www.nhsla.com/publications. There is a single template workbook encompassing the three assessment levels. The template will also facilitate the organisation in undertaking its self-assessment against the criteria at each level.
- 6.9 Before the assessment takes place the organisation should carefully study the report from the last assessment which will detail areas requiring attention.
- 6.10 The onus is on the organisation to demonstrate compliance with the risk management criteria. The organisation must draw to the attention of the assessor(s) the evidence for each of the subject areas. The time available for the assessment will not permit the assessor(s) to search for evidence. The 'reference' section of the appropriate evidence template should be completed to alert the assessor(s) to where each of the minimum requirements can be found within the documents submitted. If the evidence template has not been fully completed, and the organisation is unable to signpost the assessor(s) to the relevant evidence within the time allowed (in either electronic or hard copy format), the assessor(s) may be unable to complete the

assessment. This may result in the organisation being deemed to be at Level 0 and may lead to a refusal by the NHSLA to provide indemnity.

- 6.11 In some circumstances the evidence provided by the organisation may not provide sufficient assurance and the assessor(s) may seek further documentary evidence. To enable the assessor(s) to determine an assessment outcome, the organisation will be required to submit additional evidence well in advance of the feedback session.
- 6.12 It is assumed that responsibility for the assessment will rest with the executive director responsible for risk management within the organisation. The executive director or delegated contact person should use the notification period to ensure that all staff involved are fully briefed on the purpose of the assessment, their specific role, and the role of the assessor(s). The executive director or delegated contact person should be available during the visit to provide the necessary detail and information.
- 6.13 In most circumstances Level 1 assessments will be conducted by one assessor. All Level 2 and 3 assessments will be conducted by two assessors. As part of the ongoing development and quality assurance process of the assessment team, the assessor(s) may be accompanied by another assessor or manager, or a representative from the NHSLA or other relevant body. If this is proposed the organisation will be notified in advance.
- 6.14 For the duration of the visit, the assessor(s) will need an office to work in (with electrical power sockets for the assessor(s) laptop(s)) which is of sufficient size to accommodate interviews with relevant staff. In preparing an office for the visit the organisation is asked to consider the requirements of the Health and Safety (Display Screen Equipment) Regulations 1992 and provide a suitable desk or table with adjustable chair. If the assessor(s) is unable to work safely in the office provided they may ask for alternative accommodation. If suitable accommodation and furniture cannot be found the assessor(s) may be unable to undertake the assessment.
- 6.15 The assessor(s) may need some time alone to study the evidence thoroughly and review their findings.
- 6.16 The Patient Information Advisory Group (PIAG) has given approval, subject to certain conditions, for assessors to see confidential patient information as part of the NHSLA assessment process. One of these conditions is that the NHSLA should provide some text for organisations to include in their own patient information about how patient records and incident forms are used as part of the NHSLA assessment process. The following words are recommended:

“Use of patient information by the NHS Litigation Authority

The NHSLA has a statutory duty to manage and raise the standards of risk management throughout the NHS. In order to achieve this, all NHS trusts are assessed every few years against a set of risk management standards which are based on those factors which give rise to the greatest number and cost of claims. More information about the NHSLA risk management programme is available on its website at www.nhsla.com/riskmanagement.

As part of the assessment process, the assessors will look at a small number of sets of patient notes and a selection of incident report forms. None of these documents will be removed from the premises. The aim is to ensure that these documents are created and managed in accordance with appropriate policies and procedures: for example whether they are written clearly, signed and dated, stored securely, etc. The assessors are not concerned with individual patient details. They are all

professional people who have previously worked in NHS organisations and are now employed on behalf of the NHSLA under strict principles of confidentiality.

If you wish to object to your records being made available during an NHSLA assessment, please just notify the trust.”

With effect from 1 January 2009, the functions of the PIAG in England were transferred to the National Information Governance Board for Health and Adult Social Care.

- 6.17 During the visit, the assessor(s) may need to talk to a number of people from the organisation to clarify and support the documentation reviewed. It is preferable if these interviews can take place in the office allocated to the assessor(s) (if this is not convenient please discuss the arrangements with the assessor(s)). In addition at Levels 2 and 3, the assessor(s) will ask to visit areas of the organisation to review evidence in practice. Please note that at no time should the arrangements for the assessment visit compromise patient care in any way.
- 6.18 The assessor(s) will not normally need to take paper copies of any evidence away from the site at the end of the assessment. If it is necessary to take copies (for instance, in the case of a borderline assessment), permission will be sought.
- Electronic evidence is in many cases transferred to the assessor’s laptop with the evidence template. If this is the case, the assessor will delete the evidence once the report has been published on the NHSLA website. Any evidence stored on assessors’ laptops is subject to strict IT and data security protocols. If the organisation has any concerns about evidence being kept by the assessor it should raise these with the assessor in advance of the assessment.
- 6.19 The assessor(s) may not be able to inform the organisation of the outcome at the end of the assessment visit as on some occasions it may be necessary for the assessor(s) to review their findings with their colleagues to ensure consistency.
- 6.20 In the suggested timetable a short period is allowed at the end of days one and two of the assessment visit for informal feedback. These sessions should be limited to a maximum of six representatives from the organisation (other than with the express permission of the assessor), which should ideally include an executive director. The assessor(s) and the organisation should use this time as an opportunity to discuss any outstanding issues or concerns.
- 6.21 The outcome will be based on the evidence provided for review during the two day assessment period only.
- 6.22 In exceptional circumstances, extra time or an improvement period may be allowed after the assessment visit to enable the organisation to forward additional evidence to demonstrate compliance. If this is the case, the assessor will discuss the arrangements with the organisation at the time of the assessment.
- 6.23 Within 20 working days of the assessment date, or end of an “improvement period” if given, the organisation will receive a detailed report of the assessment outcome.
- 6.24 If the organisation has any concerns about the assessment or report it should raise these with their assessor or the [DNV Operations Manager](#) as soon as possible and no later than 20 working days after receipt of the report. If the concerns are not resolved to the organisation’s satisfaction and it feels that the assessment outcome is unjust, it may refer the matter to the NHSLA. An email or letter should be sent to the [Risk Management Director](#) as soon as possible, and no later than 40 working days following receipt of the assessment report.

NHSLA RISK MANAGEMENT STANDARDS

- 6.25 Any allegations regarding the improper conduct of risk management assessments will be dealt with in accordance with the NHSLA Complaints Policy. [A leaflet is available on the NHSLA website.](#)
- 6.26 Rare instances of inappropriate behaviour towards risk management assessors in performing their duties have made it necessary for DNV to introduce a *Procedure for Dealing with Abusive or Threatening Behaviour from External Sources*. A copy of this procedure can be obtained on request from the [DNV](#) Support Team.

7. ASSESSMENT PREPARATION

Guidance on Collating Evidence for an Assessment

This guidance aims to help organisations to prepare for an assessment by reiterating some of the pertinent points from the introductory section to the standards, and offering some tips on preparing evidence. Documentary evidence may be submitted either in paper or electronic format (or a combination of both), according to the preference of the organisation.

This guidance should be read in conjunction with the requirements of the NHSLA Risk Management Standards, ensuring that the quantity of evidence is restricted to that which demonstrates compliance with the level being assessed. For example, at Level 1 only the approved documents that demonstrate the systems in place are requested; evidence relating to implementation is not required.

During Level 2 or 3 assessments, the assessor(s) will need to refer to (but not assess) the documents required for a Level 1 assessment. This is necessary in order to determine at Level 2 whether the organisation is implementing the objectives it has set itself, and at Level 3 the system the organisation has established for monitoring compliance. On the day of the assessment, organisations being assessed at Levels 2 or 3 are required therefore to provide the Level 1 evidence template sheets, including the evidence, in addition to the template sheet for the level at which they are being assessed (either Level 2 or 3). Completing the template will serve as a self-assessment, thus enabling the organisation to determine its readiness for assessment.

Organisations are advised to prepare for an assessment well in advance. To reduce the amount of preparatory work required immediately prior to assessment, organisations are advised to maintain current versions of the Level 1 documentation (preferably attached to the evidence template sheet(s) by means of hyperlinking) on an ongoing basis. If you have any questions whilst preparing for an assessment please contact your assessor who will be happy to advise you.

Evidence in the form of Meeting Minutes

Where minutes of a committee/group are being used to demonstrate compliance with a criterion, organisations will be required to demonstrate that the committee/group is functioning effectively.

In relation to attendance and reporting arrangements, the committee should operate in accordance with its own terms of reference. A formal written record of the content and discussion of the particular committee/group should be made. The minutes should record those who attended the meeting (including their designation), the issues discussed and the actions agreed.

The number of sets of minutes required as evidence will be determined by the committee/group's own standard as outlined within its terms of reference. The organisation should present the minutes of meetings held over the previous twelve months, or as many as will be required to demonstrate that the committee/group is fulfilling its responsibilities. Full minutes should be submitted where possible. Extracts from minutes will be accepted provided that they indicate the date of the meeting and those present, and are signed as an accurate record of events by the committee/group chair.

Completion of NHSLA Evidence Template

The evidence template has been designed to assist organisations in preparing for an assessment by:

- focusing the collation of evidence on that required to demonstrate compliance with the standards;
- collating all of the required evidence into one document;
- necessitating a self-assessment to determine whether compliance can be demonstrated;
- facilitating the identification of points within the evidence which address the specific minimum requirements.

There is a single template workbook encompassing the three assessment levels. The template can be found at www.nhsla.com/publications. It is important that the 2009/10 template is completed as previous versions will not reflect the current requirements within the standards.

Failure to provide all documentation in the requested format may result in the organisation being deemed to be at Level 0 and may lead to a refusal by the NHSLA to provide indemnity.

Further information on completion of the NHSLA evidence template can be found at www.nhsla.com/publications.